

## **REMARKS**

Claims 75-115 are pending in the present application. Claims 1-78 have been cancelled. Claims 79, 98 and 109 have been amended—support is found throughout the specification, for example, page 20, entire page; page 21, last par.; and the original claim.

Reconsideration of the present application is respectfully requested.

## **Rejection under 35 USC § 103**

The Examiner has rejected claims 79-115 as unpatentable over Romanczyk, Jr. (US 5,554,645) in view of Faendriks (Derwent Acc No 1997-525196, abstract) on the ground that Romanczyk teaches a food composition comprising a cocoa polyphenol, and Faendriks *et al* teach use of L-Arginine, respectively, for the same purpose (anti-cancer/tumor) and it would have been obvious to combine the two active ingredients into one composition for anti-cancer treatment and that adjustment of the amounts/ranges of each active ingredient is deemed merely a matter of judicious selection and routine optimization to arrive at the claimed compositions.

The Examiner has failed to give due consideration to Applicants' claims by ignoring the following claim limitations and evidence on improper legal grounds:

- (i) “effective to induce vasorelaxation in a human or a veterinary animal” on the ground that it only refers to the intended use of the composition (Office Action dated March 30, 2011, page 6, last par.) (the claims now further recite the non-chocolate food product “for therapeutic induction of vasorelaxation”);
- (ii) “effective to induce vasorelaxation in a human or a veterinary animal” on further ground that the undisclosed use is inherent in the composition resulting from the combination of prior art ingredients (Office Action dated March 30, 2011, page 6, last par.);

- (iii) “up to 3 g of cocoa polyphenol per unit dose” as “not limit[ing] the instantly claimed food composition” because “one of ordinary skill in the art can utilize any arbitrary unit dose” when combining the ingredients from prior art (Office Action dated March 30, 2011, par. spanning pages 5 and 6); and
- (iv) ignoring evidence of uncertainty in the art regarding the cancer effects of L-arginine (Office Action mailed March 30, 2011, par. spanning pages 4-5).

Applicants respectfully traverse the rejection.

Regarding point (i) above, the Office fails to apply the correct legal standard as articulated by the Federal Circuit Court in a post-KSR opinion *In re Sullivan*, 498 F.3d 1345 (Fed Cir 2007), which case dealt with patentability of claims directed to antivenom compositions.<sup>1</sup> First, the Court wrote: “[w]hile a statement of intended use may not render a *known* composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence.” *Id* at 5. (emphasis added). Here, a composition comprising a combination of L-arginine and certain polyphenols as recited in the present claims was not known, *i.e.*, it did not exist as such in the prior art, thus the evidence provided by Applicants should have been considered, rather than summarily dismissed, in determining obviousness as explained by the Federal Circuit Court in *In re Sullivan*:

Furthermore, the Board’s focus on the intended use of the claimed composition misses the mark. The Board cites *In re Zierden*, 411 F.2d 1325 (CCPA 1969), for the proposition that a statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. In

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<sup>1</sup> Applicants do not enclose copies of opinions discussed herein as they believe they are readily available to the Examiner; however, for the convenience of the Examiner, Applicants can provide the copies—kindly telephone the undersigned.

that case, applicant conceded that his composition was distinguished from the composition disclosed in a prior art patent only by the statement of intended use. Our predecessor court held that that intended use for the known composition could not render the claim patentable. In this case, applicant does not concede that the only distinguishing factor of its composition is the statement of intended use and, in fact, extensively argues that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. Such a use and unexpected property cannot be ignored. See *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963) (“From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. . . . There is no basis in law for ignoring any property in making such a comparison.”). *The issue here is not whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use.* That unexpected property is relevant, and thus the declarations describing it should have been considered by the Board.

*Id.* (emphasis added). See also, *USPTO KSR Guidelines Update*, 1358 OG 398 (Sept. 28, 2010), Example 5.2. Accordingly, Applicants respectfully request consideration of all evidence of record regarding the unexpected vasodilating properties of the claimed compositions.

Regarding point (ii) above, the Office makes a legal error by applying the doctrine of inherency to an obviousness analysis—It is well established under the US Patent Law that “[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established (citation omitted).” MPEP §2141.02V. [Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result.” *In re Shetty*, 566 F.2d 81, 86 (CCPA 1997).

Regarding point (iii) above, obviousness cannot be predicated on arbitrary experimentation by a person of skill in the art, the cited prior art must suggest the

particular amounts recited in the present claims—as evidence of record shows, such amounts, effective at reducing vasorelaxation, are not suggested by the cited prior art given that vasodilating properties were not disclosed or suggested by the cited art.<sup>2</sup>

Regarding point (iv) above, the Examiner improperly ignores evidence of record regarding uncertainty in the art regarding cancer effects of L-arginine by simply asserting that *prima facie* case of obviousness was met (Office Action mailed March 30, 2011, par. spanning pages 4-5) while ignoring the rebuttal evidence Applicants made of record—rebuttal evidence must be considered.

Applicants respectfully request reconsideration of the present claims and all evidence of record in view of the correct legal standards as discussed above.

Withdrawal of the rejection is respectfully requested.

### **Conclusion**

Applicants believe that the application is in condition for allowance. An action to that effect is respectfully requested.

Respectfully submitted,

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/Nada Jain/

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<sup>2</sup> “[A] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” (see, MPEP Section 2144.05 II).